

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0000054379	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/EP2004/002582	International filing date (day/month/year) 12.03.2004	Priority date (day/month/year) 19.03.2003
International Patent Classification (IPC) or national classification and IPC		
Applicant BASF AKTIENGESELLSCHAFT		

1.	This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.																								
2.	This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.																								
3.	This report is also accompanied by ANNEXES, comprising: <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																								
4.	This report contains indications relating to the following items: <table border="0"> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I

Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-44 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. 1-30 _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets 1/2-2/2 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-30	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-30	NO
Industrial applicability (IA)	Claims	1-30	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
1. Reference to the following documents:			
D1: EP-A-O 486 290 (AMOCO CORP)			
20 May 1992 (1992-05-20)			
D2: DE 197 44 212 A (SCHERING AG)			
15 April 1999 (1999-04-15).			
2. The present application fails to satisfy the requirements of PCT Article 33(2) because the subject matter of claims 1-30 lacks novelty (PCT Article 33(2)).			
3.1 Document D1 discloses (the references in brackets are to said document) a method for the production of a variety of sterols which can be regarded as intermediate and/or resultant products of ergosta-5,7-dienol, said method involving the cultivation of organisms which have a reduced Δ^{22} -desaturase (erg5) activity and an increased HMG-CoA-reductase activity relative to the wild type (see claim 13).			
3.2 Document D2 discloses a method for the production of a variety of sterols which can be regarded as			
/...			

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

intermediate and/or resultant products of ergosta-5,7-dienol, said method involving the cultivation of organisms which have an increased HMG-CoA-reductase activity and increased squalene poxidase (erg1) activity relative to the wild type (see claim 2.a-iv)).

- 4.1 The present application fails to satisfy the requirements of PCT Article 33(1) because the subject matter of claims 1-30 does not involve an inventive step (PCT Article 33(3)).
- 4.2 Document D1 is considered to be the prior art closest to the subject matter of claim 1 and the subject matter of claim 1 therefore differs from D1 in that the method is implemented using organisms which, by comparison with the present claims, **additionally display an increased activity of a further enzyme**, which enzyme can be selected from the group comprising lanosterol-C14-demethylase (erg11), squalene poxidase (erg1) and squalene synthetase (erg9).
- 4.3 The problem addressed by the present invention can consequently be regarded as that of providing an alternative method for producing ergosta-5-7-dienol (and/or biosynthetic intermediate and/or resultant products thereof).

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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4.4 The solution proposed in claims 1-10 and 15-18 of the present application cannot be considered inventive (PCT Article 33(3)) for the following reasons:

as stated in point 3.2 above, D2 discloses (see claim 2.a-iv)) a method for the production of ergosta-5-7-dienol and/or biosynthetic intermediate and/or resultant products thereof by means of an increased t-HMG and erg1 activity. A person skilled in the art could therefore arrive at the solution to the present problem by combining the disclosures of D1 and D2, without unreasonable experimental input.

4.5 Moreover, the problem cannot be considered to have been solved for the entire scope of protection claimed in claim 1: (i) it has not been shown that the problem has been solved for all intermediate and/or resultant products of ergosta-5,7-dienol. Tables 2 and 3 (data for *S. cerevisiae* GRFtHIura3ERG1erg5) show the decrease in the content of squalene (which can be considered to be an intermediate product of ergosta-5-7-dienol) by comparison with table 1 (data for *S. cerevisiae* GRFtHIura3) and table 3 (data for *S. cerevisiae* GRFtHIura3erg5); (ii) nor has it been shown that the aforementioned problem has been solved by an increase in lanosterol-C14-demethylase (erg11) or squalene synthetase (erg9) activity (in addition

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to a reduction in erg5 activity and an increase in
HMG reductase activity).

4.6 In consequence, claims 1-30 do not involve an
inventive step (PCT Article 33(3)).

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Box No. VI **Certain documents cited**

1. Certain published documents (Rule 70.10)

Application No.
Patent No.Publication date
(day/month/year)Filing date
(day/month/year)Priority date (valid claim)
(day/month/year)

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)Date of written disclosure
referring to non-written disclosure
(day/month/year)

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box VI

Document D4 (W003/064650), cited in the search report,
might be prejudicial to novelty in a later regional
phase.